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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PALENIK, JEFFREY T	

ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,208	GLADMAN ET AL.	
	Examiner	Art Unit	
	Jeffrey T. Palenik	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *7-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,24 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicants' Amendments and Remarks filed 16 September 2008. The Examiner acknowledges the following:

Claims 1-6 have been amended. The nature of the changes made to the claims is editorial only. The scope of the claims currently under consideration has not changed.

Claims 24 and 25 have been added for which Applicants have provided support.

The Examiner acknowledges that no new matter has been added to the claims.

Thus, claims 1-6, 24 and 25 now represent all claims currently under consideration.

INFORMATION DISCLOSURE STATEMENT

No new Information Disclosure Statement (IDS) have been submitted for consideration.

WITHDRAWN OBJECTIONS/REJECTIONS

Objection to the Specification

Applicants' amendments to the Abstract of the Invention has been considered fully and is persuasive. Thus, said objection has been **withdrawn**.

MAINTAINED REJECTIONS

The following rejection is maintained from the previous Office Correspondence dated 5 March 2008 since the art which was previously cited continues to read on the amended limitations.

CLAIM REJECTIONS - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language of claim 1 is vague and indefinite because it lacks clarity. It is not immediately clear how the powder, the biliquid foam and the matrix of polymer material components relate to one another within the overall composition. The Examiner interprets the broadest reasonable definition of the claim language to read as: a polymer-encapsulated, biliquid foam.

RESPONSE TO ARGUMENTS

Applicants' argument with regard to the rejection of claim 1 under 35 USC 112, second paragraph, has been fully considered, but is not persuasive.

Applicants merely reiterate the language of the claim.

In response, the Examiner respectfully submits that the lack of definitiveness stems from the breadth of the claim, particularly the phrase "entrapped within". As stated above, the claim is accorded its broadest, most reasonable interpretation in view of said phrase.

Thus, for these reasons, Applicants' arguments are found unpersuasive. The above rejection is hereby maintained.

CLAIM REJECTIONS - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, and 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Hiestand et al. (U.S. Patent 3,549,555).

The instant claims are directed towards a powder comprised of a polymeric matrix material which further comprises an entrapped biliquid foam. Claim 2 further limits the powder composition to one that is dried by spraying, freezing or granulating in a fluidized bed. Claim 4 further limits the encapsulating polymeric material of the powder composition and claim 5 further limits the composition of the biliquid foam. The dependent claim 6 further limits the biliquid foam emulsion component of the composition such that its representative weight ranges from 5% to 50% of the composition.

Such compositions are taught by Hiestand. Claim 1 teaches a lipophilic-liquid-in-hydrophilic-liquid emulsion wherein the particles are coated with a coacervate and then hardened. Spray-drying and freeze-drying are both taught (col. 7, lines 18-23). Examples 3 and 4 also teach specifically teach spray-drying of the encapsulated material (col. 7, line 70 to col. 8, line 25). Example 4 further teaches the use of carboxymethylcellulose (CMC) as a thickener, the use of gelatin as the coacervating colloid, and the use of lanolin as the oil phase in the emulsion. Example 3 teaches the use of mineral oil in the emulsion. The example cites the following formulation:

Volume	Ingredient(s)
33 mL	Mineral oil
25 mL	Water (containing 2 gm magnesium aluminum silicate and 0.5 gm alizarin cyanide green
125 mL	Gelatin sol (12.5 gm gelatin + 125 mL water)
125 mL	20% sodium sulfate solution containing 37 gm acacia
12.5 mL	37% formaldehyde solution
320.5 mL	Total volume

Mineral oil is taught as comprising about 10.3% by weight of the oil based on the weight of the composition.

CLAIM REJECTIONS - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hiestand (U.S. Patent 3,549,555) in view of Macaulay (U.S. Patent 3,016,308)

The instant claims are directed towards a powder comprised of a polymeric matrix material which further comprises an entrapped biliquid foam or emulsion, as described above. The dependent claim 3 further limits the powder composition by its particle size, citing a range from 5 to 150 microns.

Such compositions are taught by Hiestand et al., as described above. The size of the particles (e.g. emulsion capsules) is taught to be dependent, in part, on a multitude of variables such as degree of dispersion, size of the emulsion particles of the primary emulsion and the thickness of the coacervate applied (col. 6, lines 43-54). Thus the particle thickness is governed by the ingredients used. However, Hiestand et al. does not set forth a specific target range for particle size, such as the range of the instant claim 3.

Macaulay teaches a free-flowing powder of microscopic discrete emulsion capsules (claim 11) contained by a polymeric film (col. 5, lines 43-50 and 65). Claim 11 further teaches that the resulting powder capsules will have a diameter ranging between about 0.1 to 70 microns. Claim 12 teaches a preferred diameter limitation ranging from about 1 and 20 microns.

The references do not teach the particular particle size range claimed by Applicant. The particle size of a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of such parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect

success. It would have been customary for an artisan of ordinary skill to determine the optimal particle size (e.g. diameter) of the resulting powder capsules in order to best achieve the desired results of the instant invention. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of particle size and ingredient amounts would have been obvious at the time of Applicant's invention.

RESPONSE TO ARGUMENTS

Applicants' argument with regard to the rejection of claims 1, 2 and 4-6 under 35 USC 102(b) as being anticipated by Hiestand et al., as well as to the rejection of clams 1-6 under 103 over Hiestand et al. in view of Macaulay et al. have both been fully considered, but is not persuasive.

Applicants allege that biliquid foams and emulsions are not the same. Emulsions are further defined as comprising a non-aqueous phase, an aqueous phase and a single layer of surfactant molecules which prevents coalescence. Biliquid foams comprise a second layer or "double layer" of surfactant molecules which prevent coalescence, as proposed by the literature. Furthermore, Applicants argue that usually greater than 74-98% of the total liquid volume of a biliquid foam is attributed to the dispersed phase and that this leads to a "robustness and stability" in the foam composition as opposed to the emulsion composition.

In response to Applicants' argument that the references fail to show certain features of Applicants' invention, it is noted that the features upon which Applicants rely (i.e., surfactant double layer and percent dispersed phase) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read

into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, the Office does not have the facilities for examining and comparing the alleged differences between biliquid foams and emulsions in order to establish that the products of the prior art do not possess the same material structural and functional characteristics of the claimed composition. In the absence of evidence to the contrary, the burden is upon Applicants to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 USPQ2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Thus, for these reasons, Applicants' arguments are found unpersuasive. The above rejection is hereby maintained.

RESPONSE TO LACK OF UNITY REMARKS

Applicants' traverse the lack of unity requirement on the grounds that Macaulay (USPN 3,016,308) "does not disclose microscopic capsules containing an emulsion" and that the patent is silent with respect to biliquid foams.

The Examiner respectfully disagrees and submits that Figure 1 and the description thereto set forth such a structure. The figure depicts a single granule of the free-flowing powder composition which is formed wherein the marking fluid emulsion (10) is contained by in a shell (11) which is comprised of polymeric materials such as those which are instantly claimed such as carboxymethylcellulose and methylcellulose (col. 5, lines 43-51). Applicants' traversal to biliquid foams is discussed above.

Thus, for these reasons, Applicants' arguments are found unpersuasive. The above lack of unity is hereby maintained.

NEW REJECTIONS

In light of Applicants' amendments, most notably the addition of claims 24 and 25, the following rejections have been newly added:

CLAIM REJECTIONS - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New claims 24 and 25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the limited range of "one or more pharmaceuticals", such as ibuprofen (see Preparation 9, pg. 17), does not reasonably provide enablement for the incorporation of broader limitation of "contains pharmaceuticals", as further limited in the instant claim 25. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The limitation "contains pharmaceuticals" is extremely broad and encompasses an equally broad range of potential drug combinations, none of which are discussed by the instant disclosure. Given its broadest reasonable interpretation, the recitation "contains pharmaceuticals", is deemed by the Examiner as directed towards the concurrent containment of two or more pharmaceuticals. To this end, given that the instant invention provides support for

the incorporation of only one drug within the composition, the Examiner respectfully submits that one of ordinary skill in the art would be faced with an undue experimental burden in attempting to practice the invention commensurate in scope with the claims. That is, the instant invention is seemingly concerned with an extremely limited subclass of pharmaceuticals, and an ordinary practitioner would need to undergo undue experimentation in order to develop the instantly claimed composition without seeking further guidance from the prior art. As such, the disclosure of the instant specification is not sufficient to support the generically claimed limitation of "contains pharmaceuticals".

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Hiestand et al. as set forth above with respect to claim 1.

The water-immiscible phase of the composition of claim 1 is recited as comprising one or more pharmaceuticals.

The teachings to Hiestand are discussed above. Additionally, it is taught that the encapsulated emulsion can be prepared containing appropriate materials in the emulsion phases for the purposes of sustained release. Said materials are taught as being fertilizers, pesticides, vitamins and pharmaceuticals (col. 3, lines 36-60).

Though Hiestand does not expressly teach incorporating any of the above types of compounds specifically into the water-immiscible phase of the composition, it would have been *prima facie* obvious to a person of ordinary skill in the art to do so particularly because both phases of the emulsion are taught as having ingredients (i.e. pharmaceuticals) suspended or dissolved within (col. 4, lines 15-20). Thus, the ordinarily skilled artisan would be highly motivated to dissolve or suspend one or more pharmaceutical compounds within the water immiscible phase of the composition and have a reasonably high expectation of success at arriving at the instantly claimed invention.

All claims have been rejected; no claims are allowed.

CONCLUSION

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615